design ✦ specific

K101723

DEC 2 3 2010

Summary 510(k) Submission

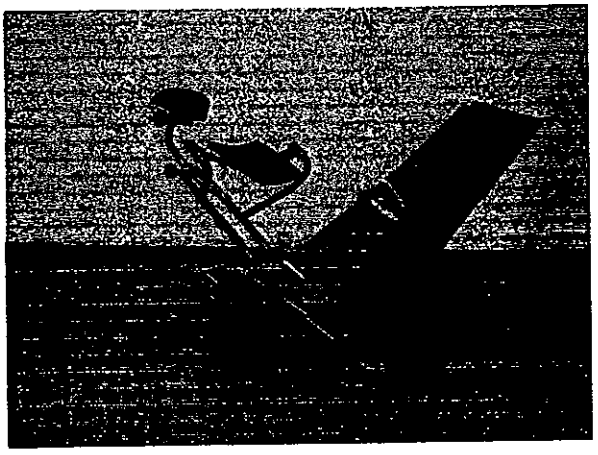
Compact Wheelchair Platform

Device name and contacts

Device Name	'Compact Wheelchair Platform'
Contact	Mr. Richard Fletcher Design Specific Ltd Unit 10 Caburn Enterprise Park The Broyle Ringmer East Sussex BN8 5NP
Trade Name	Compact Wheelchair Platform
Common Name	Wheelchair Reclining Platform
Classification Code	890.3110 Class II
Date prepared	21.4.10

R. Fletcher
17.10.07

Trade Name	Compact Wheelchair Platform
Common Name	Wheelchair Reclining Platform
Classification Name	Dental Chair and Accessories (CFR 890.3110 Class II)
Equivalence	Mobile wheelchair Platform Design Specific Ltd K073565



Description

The Compact Wheelchair Platform (CWP) is designed to assist in the clinical treatment of wheelchair users by providing a convenient wheelchair accessible platform that can be tilted so that the head is placed in the optimum position of comfort for both staff and patient. It is a direct development of the Mobile Wheelchair Platform (K073565)

The 'Mobile wheelchair Platform' received good reviews but users expressed a need for a smaller lighter platform that would require a smaller space when not in use. The increase in body mass of the general population required that the new platform should be able to carry higher loads. The complete redesign more than halved the storage area and up-graded the load from a SWL of 594lb to 660lbs. The unit being tested to 825lbs. The angle of tilt has been altered to 60deg to provide a recovery position.

The clinician operating position is optimal. After tilting to 45 degrees the patient's head height is only 800mm, quite low enough for normal seated working. Clinical opinion indicates that this head height and angle of tilt is comparable with that desired for optimal

work, however a large number of clinicians prefer a smaller angle of tilt. A clinical stool with a pump-up rise and fall motion can be used to optimise the seating position if desired

By utilising extensive clinical feedback Design Specific has been able to develop a backrest assembly that has vertical adjustment to accommodate a wide range of patient statures in comfort. The previous Mobile platform had a fixed height backrest.

Design

The Wheelchair platform is supported on two side frames with a high pivot point. The hydraulic cylinders are below the pivot and retract to tilt the platform. This gives a very compact form and with a hinged platform base the whole unit is no more than 24" wide. It can be easily moved through doors for sharing with other opertories. The whole construction is aerospace high strength aluminium alloys or stainless steel giving a high strength weight ratio.
The unit is powered at 24v. The main source of power is from a pair of 12v lead acid batteries that can be easily replaced and last for at least 40 full cycles before needing to be recharged. A dc supply is provided to operate the machine from the mains supply if needed.

The control is via a PCB with a PIC logic controller. All switching takes place at 5v and makes the controls light and reliable. The logic capability allows continuous monitoring of safety switching and the integration of good safety procedures. A radio handset is normally used to control the platform eliminating any trailing wires

Safety is a major concern and entrapment is eliminated by using sensitive, fail-safe, strip switches at all sensitive points on the mechanism. . The radio handset and fixed switches on the machine are supplied to operate the device, duplicating the control function. All control and drive elements are housed safely under a cover. The machine has clean lines and is easily cleaned with wipe over surfaces.

Intended use

The wheelchair Platform is to treat patients that cannot reasonably be removed from their chairs and transported to another device. The concerns would include health and safety of the clinical staff and the patients, medical conditions of the patient and the special nature of some wheelchairs. Clinical environments, particularly dental opertories, would be high in the order of need others would be Maxio facial, ear nose and throat, eye treatments.

Technical Characteristics

Characteristic	Design Specific Wheelchair Platform	Compact Wheelchair Platform
Basic Platform Shape	Steel Fabrication	Aluminium and Stainless steel
Drive mechanism	Electrical Linear Drive	Hydraulic operation
Power source	Battery 24v and Power supply delivering 24v	Battery 24v and Power supply delivering 24v
Backrest support	Pivots in and out adjustable by worm and wheel. Fixed height backrest pad	Pivots in and out adjustable by worm and wheel. Adjustable height backrest pad
Headrest	Adjustable using a slotted arm with an adjustable headrest cushion for neck and head support.	Adjustable using a slotted arm with an adjustable headrest cushion for neck and head support
Wheelchair type	All types including battery driven wheelchairs and specially moulded chairs	All types including battery driven wheelchairs and specially moulded chairs
Command input	Fixed switches on the mechanism cover and remote radio transmitter handset.	Fixed switches on the mechanism cover and remote radio transmitter handset.
Foot crush protection	Pressure sensitive mat and guarding	Pressure sensitive strip switches
Max. angle of tilt	45deg	60deg
Rated capacity	594lb (BSEN1570:1999)	660lb (BSEN1570:1999)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Design Specific Ltd.
% Mr. Richard Fletcher
Unit 10 Caburn Enterprise Park The Broyle
Ringmer East Sussex
United Kingdom BN8 5NP

DEC 2 3 2010

Re: K101723
Trade/Device Name: Compact Reclining Wheelchair Platform
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: Class II
Product Code: INO
Dated: October 18, 2010
Received: November 3, 2010

Dear Mr. Fletcher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number: K101723

DEC 2 3 2010

Device Name: Compact Reclining Wheelchair Platform

Indications for use:

The clinical treatment of persons in wheelchairs presents a significant issue for clinicians and patients alike. Procedures related to a patient's head often require them to be reclined. A platform for reclining the wheelchair giving full support to both chair and patient provides a safer working environment for both patient and clinician. The hazards associated with transfers to other couches or chairs are eliminated.

Typical treatments would include:

- Dental
- Maxiliofacial work
- Ear, Nose and Throat procedures
- Eye treatments and surgery
- Podiatry

Prescription Use X AND/OR Over-The-Counter Use X,
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS) LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
Restorative Devices

510(k) Number K101723